

REMARKS

In the application, Claims 3, 6-21 and 23 are pending and rejected. It is noted that the finality of the previous office action has been withdrawn. The newly applied rejections and objections raised in the Office Action of February 5, 2003 have been considered and, in response, the claims have been amended. It is submitted that the claims now presented are in a condition for allowance and the Examiner is requested to reconsider the claims and issue a notice of allowance.

Amendments to the specification have been made to correct minor typographical and grammatical error. No new matter is added.

The Examiner rejects Claims 3, 6-21 and 23 under 35 U.S.C. §112, 1st para. as containing subject matter which was not described in such a way as to enable one skilled in the art ... to make and/or use the invention. In particular, the Examiner relies on the conclusion in the article by Stoeckert, et al. to support a position that the usage of gene expression profiles generated on microarrays are unpredictable.

The Examiner is requested to direct his attention to the "Background of the Invention" of the present application at page 5, where Applicants, themselves, point out the inadequacies of several known techniques for gene expression monitoring due to their limited quantitative reproducibility, and because hybridization techniques are generally only useful to analyze expression of genes whose sequences are already known. Further described in the background is a reproducible technique for profiling gene expression with *great quantitative accuracy*, i.e., predictability, which is disclosed in International Publication No. WO 97/05286, which disclosure is incorporated in the application. It is submitted that the Stoeckert, et al. article conclusion of a lack of common standards and ontologies refers only to the goal of a broadly accessible database for all data generated using microarrays. For example, the authors refer to the tendency of scientists to normalize data which can affect how the data is characterized in comparison with other data. These issues have no bearing on whether Applicants' invention as disclosed can be practiced for purposes of performing comparisons on expression data contained in one or more databases in which the data was generated using similar protocols and procedures. For example, all data may have been generated using Affymetrix Gene Chip® microarrays and the Affymetrix LIMS (laboratory information management system), which are widely used. It would be readily apparent to those in the art that some commonality as to the

origin of the data would be important. An exemplary procedure for obtaining the gene expression data is provided in the description. The description is not non-enabling merely because it does not describe how to analyze and display gene expression data generated by every possible method for measuring gene expression on a microarray or use a universal ontology or other form of standardization. The claimed invention provides for analysis and display of expression data. Applicants do not claim to have solved any or all issues raised in the Stoeckert et al. article regarding global standardization of data and ontology. Accordingly, Applicants respectfully submit that the invention as claimed is enabled in the written description and request that the Examiner withdraw the rejection for lack of enablement.

The Examiner rejects Claims 3 and 6-21 under 35 U.S.C. §112, 2nd para. as being indefinite.

In response, the claims have been amended to address the instances of lack of clarity and missing antecedent basis identified by the Examiner.

The Examiner rejects Claims 6 and 23 under 35 U.S.C. §103(a) as being unpatentable over Farr et al. (Pat. No. 5,811,231) in view of the decision in *In re Venner* (120 U.S.P.Q. 192, *et seq.*).

The Examiner did not reject Claim 3 over the teachings of Farr et al.. A notable distinction between Claim 3 and Claims 6 and 23 is the inclusion of limitations relating to the nature of the characteristics of the first and second polynucleotides. Accordingly, Claims 6 and 23 have been amended to include the descriptions of the first and second polynucleotide characteristics. It is submitted that these amendments render the invention as claimed in Claims 6 and 23 patentably distinct over the teachings of Farr et al.

In view of the foregoing amendments and remarks, Applicants submit that all bases for rejection have been addressed and overcome such that the amended claims are allowable over the prior art. Accordingly, Applicants respectfully request that the Examiner withdraw all rejections set forth in the Office Action and issue a notice of allowance for all claims now in the application.

Should the Examiner believe that prosecution of this application might be expedited by further discussion of the issues, he is invited to telephone the undersigned attorney for Applicants at the telephone number indicated below.

Respectfully submitted,

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